

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using VORANIGO?

VORANIGO contains the active ingredient vorasidenib. VORANIGO is used to treat, following surgery, specific brain cancers (astrocytoma or oligodendroglioma) that contain a particular mutated (abnormal) form of the isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) enzyme. VORANIGO is used in adults and adolescents aged 12 and over. For more information, see Section [1. Why am I using VORANIGO?](#) in the full CMI.

### 2. What should I know before I use VORANIGO?

Do not use if you have ever had an allergic reaction to vorasidenib, the active ingredient in VORANIGO, or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see [Section 2](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with VORANIGO and affect how it works. A list of these medicines is in [Section 3](#) in the full CMI.

### 4. How do I use VORANIGO?

The usual dose of VORANIGO in adults and adolescents 12 years of age and older is:

- 40 mg taken orally once daily for patients weighing at least 40 kg
- 20 mg taken orally once daily for patients weighing less than 40 kg

The tablets should be taken once daily at about the same time each day. You should not eat food at least 2 hours before and 1 hour after taking VORANIGO. More instructions can be found in Section [4. How do I use VORANIGO?](#) in the full CMI.

### 5. What should I know while using VORANIGO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using VORANIGO.</li><li>• Take all blood tests including liver function tests as directed by your doctor (prior to starting treatment, every 2 weeks during the first 2 months of the treatment and then once monthly throughout the duration of the treatment or as directed by your doctor).</li><li>• If you or your partner use a hormonal contraceptive, you must also use effective barrier method contraception (e.g. condoms or a diaphragm) during treatment with VORANIGO and for at least 3 months after the last dose.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using VORANIGO suddenly without consulting your doctor.</li><li>• You should not take VORANIGO together with certain medicines. Some medicines may affect how VORANIGO works for you and VORANIGO may affect how other medicines you take work for you. See further information in Section <a href="#">3. What if I am taking other medicines?</a></li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• VORANIGO is not likely to affect your ability to drive or use any tools or machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a cool dry place below 30°C. Keep Out of Reach of Children.</li><li>• Once opened, VORANIGO should be used within 60 days. Close the bottle tightly.</li></ul>

For more information, see Section [5. What should I know while using VORANIGO?](#) in the full CMI.

### 6. Are there any side effects?

VORANIGO is usually well tolerated, however all medications may have unwanted effects in some people. The most common serious side effect is increased liver enzymes in the blood. Symptoms may include yellowing of your skin or the white part of your eyes (jaundice), dark 'tea-coloured' urine, loss of appetite, pain on the upper right side of your stomach area, feeling very tired or weak. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# VORANIGO®

Active ingredient: *Vorasidenib*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using VORANIGO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VORANIGO.**

**Where to find information in this leaflet:**

1. [Why am I using VORANIGO?](#)
2. [What should I know before I use VORANIGO?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use VORANIGO?](#)
5. [What should I know while using VORANIGO?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using VORANIGO?

VORANIGO is a cancer medicine that contains the active substance vorasidenib. It is used to treat specific cancers of the brain with changed (mutated) genes that make proteins known as IDH1 or IDH2, which play an important role in making energy for cells. When the IDH1 gene or IDH2 gene is mutated, the IDH1 or IDH2 protein is changed and does not function properly. This results in changes in the cell that can lead to the development of cancer. VORANIGO blocks the mutated form of the IDH1 or IDH2 protein and helps to slow or stop the cancer from growing. VORANIGO is used to treat adults and adolescents from 12 years of age and older with cancers of the brain called astrocytoma or oligodendroglioma following surgery.

This medicine is only used in patients whose brain cancer is related to a change (mutation) in the IDH1 or IDH2 protein.

Your doctor will perform a test to check if your cancer has an IDH1 or IDH2 mutation to make sure that VORANIGO is the right treatment for you.

**Speak to your doctor if you have any questions about this test and the results.**

## 2. What should I know before I use VORANIGO?

There are some people who should not take VORANIGO. Please read the list below. If you think any of these situations apply to you or you have any questions, please see your doctor.

## Warnings

**Do not use VORANIGO if:**

- you are allergic to vorasidenib, the active ingredient in VORANIGO, or any of the other ingredients listed in section 7. Product details
- you are pregnant or plan to become pregnant
- you have a rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption, as VORANIGO contains lactose
- you are under 12 years of age.

## Precautions when taking VORANIGO

- Blood tests including liver function tests (ALT, AST and total bilirubin) must be monitored before starting VORANIGO, every two weeks for the first 2 months of treatment and then monthly throughout the duration of the treatment or as clinically indicated.
- The dose of VORANIGO may be reduced, stopped temporarily or permanently according to your liver function test results.

## Check with your doctor if:

- you have severe liver problems as you may be treated with VORANIGO only after careful risk/benefit assessment and will be closely monitored
- you have kidney problems
- you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

It is important to tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

## Pregnancy

VORANIGO is not recommended for use during pregnancy as it may harm the unborn baby. People of child-bearing age should have a pregnancy test prior to starting treatment with VORANIGO and should avoid becoming pregnant during therapy.

If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Contact your doctor immediately if you become pregnant whilst taking VORANIGO.

As VORANIGO may affect an unborn developing baby, it is important for women not to become pregnant for at least 3 months after treatment discontinuation.

### Contraception in women and men

People who might become pregnant, and people who have partners who might become pregnant, should use effective contraception during treatment with VORANIGO and for at least 3 months after the last dose.

VORANIGO may stop hormonal contraceptives from working properly. If you or your partner use a hormonal contraceptive (e.g. birth control pills, or contraceptive patches or implants), you should also use a barrier method (e.g. condoms or a diaphragm) to avoid pregnancy. Talk to your doctor about the right contraceptive method for you and your partner.

### Breastfeeding

It is not known if VORANIGO passes into breast milk. Do not breastfeed your baby during treatment with VORANIGO and for at least 2 months after the last dose.

### Fertility

It is not known if VORANIGO affects fertility. If you are concerned about your fertility whilst taking VORANIGO talk to your doctor.

### Elderly

No dose adjustment for patients 65 years and above.

### Children

Do not give this medicine to children under 12 years old because there is no information about its use in this age group.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

This is because they may reduce how well VORANIGO works or increase the risk of side effects, or VORANIGO may affect the way these other medicines work.

In particular, tell your doctor if you are taking any of the following medications:

#### Medicines that may increase the effect of VORANIGO include:

- fluvoxamine (medicine used for depression)
- ciprofloxacin (antibiotics used for bacterial infections)

#### Medicines that may reduce the effect of VORANIGO include:

- phenytoin (medicine used for epilepsy)
- rifampicin (antibiotics used for bacterial infections)

#### VORANIGO may decrease the effect of these medications:

- alfentanil, midazolam (medicine used for anaesthesia in surgery)
- carbamazepine (medicine used for epilepsy)
- ciclosporin, everolimus, sirolimus, tacrolimus (medicines used after organ transplants known as immunosuppressants)
- fentanyl (medicine used for severe pain)
- ifosfamide, ibrutinib (medicines used for cancer)
- tamoxifen (medicine used to prevent breast cancer)
- darunavir (medicine used for HIV)
- hormonal contraceptives.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VORANIGO.**

## 4. How do I use VORANIGO?

### How much to take / use

Always take this medicine exactly as your doctor has instructed. Check with your doctor if you are unsure.

The recommended dose is:

- 40 mg orally once daily if you weigh at least 40 kg
- 20 mg orally once daily if you weigh less than 40 kg

You should not eat food at least 2 hours before and 1 hour after taking VORANIGO, as it can affect how this medicine works. Swallow the tablets whole with water. Do not split, crush or chew the tablets.

Do not swallow the silica gel desiccant found in the bottle. The silica gel desiccant helps protect the tablets from moisture. (See Section 5. What should I know while using VORANIGO?)

If you vomit after taking your usual dose, do not take additional tablets. Take your next dose as usual on the following day.

### When to take VORANIGO

VORANIGO should be taken once daily orally at about the same time each day.

### If you forget to take VORANIGO

If a dose is missed or not taken at the usual time (within 6 hours), take the tablets as soon as possible.

If you missed by more than 6 hours, you should skip the tablets and take the next dose as usual on the following day.

### If you take too much VORANIGO

If you think that you have taken too much VORANIGO, you may need urgent medical attention.

#### You should immediately do one of the following:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do one of the above even if there are no signs of discomfort or poisoning.

## 5. What should I know while using VORANIGO?

### Things you should do

#### Regular Tests

You will be monitored closely by your doctor before and during treatment with VORANIGO.

You will need to have regular blood tests of your liver function, including ALT, AST and total bilirubin before starting VORANIGO, every 2 weeks during the first 2 months of treatment and then monthly throughout the duration of the treatment or as clinically indicated.

The dose of VORANIGO may be reduced, VORANIGO may be stopped temporarily or permanently according to your liver function test results.

#### Call your doctor straight away or go straight to the Emergency Department if you experience any serious side effects:

Remind any doctor, dentist or pharmacist you visit that you are using VORANIGO.

#### Things you should not do

Do not stop using VORANIGO suddenly without consulting your doctor.

#### Driving or using machines

This medicine is not likely to affect your ability to drive or use any tools or machines, but if you feel unwell after taking VORANIGO, do not drive or use any tools or machines until you feel well again.

#### Drinking alcohol

##### Tell your doctor if you drink alcohol.

Drinking alcohol could worsen certain side effects that you may have with VORANIGO.

#### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 30°C. Do not store it in the refrigerator, bathroom, near a sink, in the car, or on windowsills.

Keep the bottle tightly closed.

#### Keep Out of Reach of Children.

#### When to discard your medicine

Once opened, VORANIGO should be used within 60 days.

Do not use this medicine after the expiry date which is printed on the bottle label and box after the expiry date.

The expiry date is the last day of the printed month.

## Getting rid of any unwanted medicine

If you no longer need to use VORANIGO or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. Some side effects may need medical attention.

Ask your doctor or pharmacist if you have any further questions about side effects after reading the below information.

### Serious side effects

Serious side effects	What to do
<p>Very common (may affect more than 1 in 10 people):</p> <ul style="list-style-type: none"> <li>• Increased amount of liver enzymes (ALT, AST, GGT) in blood. Symptoms may include yellowing of your skin or the white part of your eyes (jaundice), dark 'tea-coloured' urine, loss of appetite, pain on the upper right side of your stomach area, feeling very tired or weak)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

### Less serious side effects

Less serious side effects	What to do
<p>Very common (may affect more than 1 in 10 people):</p> <ul style="list-style-type: none"> <li>• Diarrhoea</li> <li>• Decreased count of blood platelets that can cause bleeding and bruising</li> </ul> <p>Common (may affect up to 1 in 10 people):</p> <ul style="list-style-type: none"> <li>• Increased blood sugar levels (hyperglycaemia)</li> <li>• Decreased appetite</li> <li>• Low blood phosphate levels that can cause confusion or muscle weakness (hypophosphataemia)</li> </ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you or if you do not understand something in this list.</b></p>

### Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

VORANIGO is only available with a doctor's prescription.

### What VORANIGO contains

<b>Active ingredient (main ingredient)</b>	Vorasidenib
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose Croscarmellose sodium Silicified microcrystalline cellulose Magnesium stearate Sodium lauryl sulfate Hypromellose Titanium dioxide Macrogol 400 Lactose monohydrate OPACODE WB monogramming ink NS-78-17821 BLACK

**Do not take this medicine if you are allergic to any of these ingredients.**

### What VORANIGO looks like

#### 10 mg film-coated tablets

White to off-white, round, film-coated tablets, imprinted with '10' in black ink on one side and plain on the other side.

#### 40 mg film-coated tablets

White to off-white, oblong, film-coated tablets, imprinted with '40' in black ink on one side and plain on the other side.

VORANIGO is available in a white, high-density polyethylene (HDPE) bottle with polypropylene (PP) child resistant closure and polyethylene (PE) faced induction heat seal liner. Each bottle contains 30 film-coated tablets and a silica gel desiccant in a HDPE canister. The bottles are packaged in a cardboard box; each box contains 1 bottle.

VORANIGO is registered on the Australian Register of Therapeutic Goods. Australian Register Numbers:

VORANIGO 10mg: AUST R 435450

VORANIGO 40mg: AUST R 438499

### Who distributes VORANIGO

Servier Laboratories (Aust.) Pty. Ltd.

[www.servier.com.au](http://www.servier.com.au)

Level 4, Building 9

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Burnley, 3121, Victoria

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